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09/536,762	03/28/2000	Akio Yamanishi	44319-051	5310

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MCDERMOTT WILL & EMERY
600 13TH STREET, N.W.
WASHINGTON, DC 20005-3096

EXAMINER	
KREMER, MATTHEW J	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/536,762	Applicant(s) YAMANISHI, AKIO
	Examiner Matthew J Kremer	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-12 and 20-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3,21,23,25 and 26* is/are allowed.

6)☐ Claim(s) *4-10,12 and 20* is/are rejected.

7)☒ Claim(s) *2,11,22 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claims 4, 9, 22, and 24 are objected to because of the following informalities. In claim 4, line 2, "whit" should be "white". In regard to claim 9, line 2, "by bilirubin" should be inserted after "hardly absorbable". In regard to claim 22, line 2, "whit" should be "white". In regard to claim 24, line 2, "by bilirubin" should be inserted after "hardly absorbable". Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 20 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,770,454 to Esenpreis et al. Essenpries et al. teaches an apparatus for measuring bilirubin. (claim 4 of Essenpries et al.). Essenpries et al. teaches a light source. (column 8, lines 54-55 of Essenpries et al.). The light directed at the tissue has multiple wavelengths. (column 5, lines 50-52 of Essenpries et al.). The apparatus includes a light emerging port 17 and

light incident ports 18 and 18'. (Fig. 2 of Essenpries et al.). Each light incident port reads in multiple wavelengths. (column 3, lines 62-67 of Essenpries et al.). There are two signal generators 48 and 48'. (column 10, lines 2-8 of Essenpries et al.). There is a calculator 49 and 50. (column 7, line 65 to column 8, line 29 of Essenpries et al.).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,770,454 to Essenpreis et al. as applied to claim 20, in view of U.S. Patent 5,553,613 to Parker, and further in view U.S. Patent 5,348,003 to Caro. Essenpries et al. does not teach a light emitter that includes a white light source. Essenpries et al. teaches a primary light source that emits two wavelengths. (column 5, lines 50-52 of Essenpries et al.). It is well known in the art to use a white light source to deliver light with multiple wavelengths to a human subject due to its low cost. (column 5, lines 32-34 of Parker). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the white light source of Parker in the apparatus of Essenpries et al. since a white light source has a low cost. The combination does

not teach the use of a beamsplitter and four photoelectric conversion devices. The combination teaches the use of detection means. (column 10, lines 2-8 of Essenpries et al.). The combination teaches that the detection means includes a detection guide and a light detector. (column 7, lines 46-50 of Essenpries et al.). The combination teaches that there are different measurement values at each detection site for each wavelength. (column 3, lines 62-67 of Essenpries et al.). It is known in the art that beamsplitters and detector arrays are used to detect different wavelengths that travel through detection fibers. (column 10, line 41 to column 11, line 27 of Caro). The use of beamsplitters and detector arrays would achieve the measurement values required by the combination. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use beamsplitters and detector arrays for each collection fiber of combination as disclosed by Caro since the combination requires a system to obtain measurement values from the collection fibers and Caro teaches one such system.

6. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,770,454 to Essenpreis et al. as applied to claim 20, in view U.S. Patent 5,348,003 to Caro. Essenpries et al. does not teach a first and second light source. Essenpries et al. teaches a primary light source that emits two wavelengths. (column 5, lines 50-52 of Essenpries et al.). Essenpries et al. further discloses that light emitting diodes (LEDs) are suitable light sources. It is well known in the art to use multiple LEDS to deliver light with multiple

wavelengths to a human subject. (Fig. 4 of Caro). Such a system of irradiation would fulfill the requirements of delivering primary light as required by Essenpries et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use multiple LEDs as disclosed by Caro in the apparatus of Essenpries et al. since Essenpries et al. requires a light delivery system of delivering light of multiple wavelengths to a subject and Caro teaches one such light delivery system. The combination teaches the use of an emission controller. (Fig. 2 of Caro). The combination does not teach the use of a beamsplitter and four photoelectric conversion devices. The combination teaches the use of detection means. (column 10, lines 2-8 of Essenpries et al.). The combination teaches that the detection means includes a detection guide and a light detector. (column 7, lines 46-50 of Essenpries et al.). The combination teaches that there are different measurement values at each detection site for each wavelength. (column 3, lines 62-67 of Essenpries et al.). It is known in the art that beamsplitters and detector arrays are used to detect different wavelengths that travel through detection fibers. (column 10, line 41 to column 11, line 27 of Caro). The use of beamsplitters and detector arrays would achieve the measurement values required by the combination. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use beamsplitters and detector arrays for each collection fiber of combination as disclosed by Caro since the combination requires a system to obtain measurement values from the collection fibers and Caro teaches one such system.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,770,454 to Essenpreis et al. in view U.S. Patent 5,348,003 to Caro as applied to claim 6, and further in view of U.S. Patent 5,830,132 to Robinson. The combination does not teach the use of blue and green or red light for the determination of bilirubin. The combination teaches that the wavelengths of interest lie between 300 nm and several thousand nm. (column 2, lines 16-21 of Essenpries et al.). The combination teaches that bilirubin can be determined using a plurality of wavelengths in a known manner such as a multivariate analysis. (column 5, lines 60-67 of Essenpries et al.). Robinson teaches that the wavelength region of interest will be 300-1000 nm for bilirubin. (column 27, lines 6-20 of Robinson). Robinson further teaches that there is a significant absorption peak at 454 nm (blue wavelength) for bilirubin. Robinson also teaches that a discrete number of LEDs such as 20 can be used (column 17, lines 61-65). Using 20 LEDs over the span of 300-1000 nm, the result would be center wavelengths every 35 nm. Using 454 nm for the one wavelength as recommended by Robinson and using 35 nm increments, it would be obvious the other wavelengths would be 314, 349, 384, 419, 454, 489, 524, 559, 594, 629, 664, 699, 734, 769, 804, 839, 874, 909, 944, and 979. These wavelengths include: three red wavelengths (664, 699, 734), two blue wavelengths (454, 489), and two green wavelengths (524, 559). Robinson teaches the use of the multivariate analysis using these wavelengths for the determination of bilirubin. Such wavelengths and multivariate analysis would fulfill the requirements

suggested by Essenpries et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the wavelengths and multivariate analysis as disclosed by Robinson et al. in the combination since Essenpries et al. teaches that a plurality of wavelengths and multivariate analysis can be used for the determination of bilirubin and Robinson et al. teaches such wavelengths and analysis.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,770,454 to Essenpreis et al. as applied to claim 20 in view of U.S. Patent 5,830,132 to Robinson. Essenpreis et al. does not teach the use of blue and green or red light for the determination of bilirubin. The Essenpreis et al. teaches that the wavelengths of interest lie between 300 nm and several thousand nm. (column 2, lines 16-21 of Essenpries et al.). The Essenpreis et al. teaches that bilirubin can be determined using a plurality of wavelengths in a known manner such as a multivariate analysis. (column 5, lines 60-67 of Essenpries et al.). Robinson teaches that the wavelength region of interest will be 300-1000 nm for bilirubin. (column 27, lines 6-20 of Robinson). Robinson further teaches that there is a significant absorption peak at 454 nm (blue wavelength) for bilirubin. Robinson also teaches that a discrete number of LEDs such as 20 can be used (column 17, lines 61-65). Using 20 LEDs over the span of 300-1000 nm, the result would be center wavelengths every 35 nm. Using 454 nm for the one wavelength as recommended by Robinson and using 35 nm increments, it would be obvious the other wavelengths would be 314, 349, 384,

419, 454, 489, 524, 559, 594, 629, 664, 699, 734, 769, 804, 839, 874, 909, 944, and 979. These wavelengths include: three red wavelengths (664, 699, 734), two blue wavelengths (454, 489), and two green wavelengths (524, 559). Robinson teaches the use of the multivariate analysis using these wavelengths for the determination of bilirubin. Such wavelengths and multivariate analysis would fulfill the requirements suggested by Essenpries et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the wavelengths and multivariate analysis as disclosed by Robinson et al. in the combination since Essenpries et al. teaches that a plurality of wavelengths and multivariate analysis can be used and Robinson et al. teaches such wavelengths and analysis. In regard to claim 9, it is known in the art that for bilirubin, there is high absorptivity at 450 nm and low absorptivity around 560 nm (U.S. Patent 5,791,345 to Ishihara et al.). Robinson explicitly states that 454 nm should be used which has high absorptivity. The combination includes 559 nm which inherently has low absorptivity.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,770,454 to Essenpreis et al. as applied to claim 20 in view of U.S. Patent 5,830,132 to Robinson, and further in view of U.S. Patent 5,879,294 to Anderson et al. The Essenpreis et al. does not teach the use of blue and green or red light for the determination of bilirubin. The Essenpreis et al. teaches that the wavelengths of interest lie between 300 nm and several thousand nm. (column 2, lines 16-21 of Essenpries et al.). The Essenpreis et al. teaches that

bilirubin can be determined using a plurality of wavelengths in a known manner such as a multivariate analysis. (column 5, lines 60-67 of Essenpries et al.). Robinson teaches that the wavelength region of interest will be 300-1000 nm for bilirubin which covers the entire visible spectrum. (column 27, lines 6-20 of Robinson). Robinson further teaches that there is a significant absorption peak at 454 nm (blue wavelength) for bilirubin. Robinson also teaches that a discrete number of LEDs such as 20 can be used (column 17, lines 61-65). Using 20 LEDs over the span of 300-1000 nm, the result would be center wavelengths every 35 nm. Using 454 nm for the one wavelength as recommended by Robinson and using 35 nm increments, it would be obvious the other wavelengths would be 314, 349, 384, 419, 454, 489, 524, 559, 594, 629, 664, 699, 734, 769, 804, 839, 874, 909, 944, and 979. These wavelengths include: three red wavelengths (664, 699, 734), two blue wavelengths (454, 489), and two green wavelengths (524, 559). Robinson teaches the use of the multivariate analysis using these wavelengths for the determination of bilirubin. Such wavelengths and multivariate analysis would fulfill the requirements suggested by Essenpries et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the wavelengths and multivariate analysis as disclosed by Robinson et al. in the combination since Essenpries et al. teaches that a plurality of wavelengths and multivariate analysis can be used and Robinson et al. teaches such wavelengths and analysis. The combination does not teach calculating 1-4 products by multiplying 1-4 constants by 1-4 electrical signals, a calculation of the logarithmic number of a quotient

obtained by division of the second product by the first product, a calculation of a logarithmic number of a quotient obtained by division of the fourth product by the third produce, and calculation of a bilirubin concentration based on the difference. The combination teaches that quantitative analysis of the processed spectra is performed by a central processing unit in conjunction with a multivariate calibration model and algorithms and the results are in a memory storage unit. (column 24, lines 1-12 of Robinson). It is well known in the art that the steps for processing signals includes using an empirically determined absorption coefficient which is multiplied by the optical absorption value to help determine the analyte concentration. (column 1, lines 36-48 of Anderson). Anderson further discloses that ratios of absorption of measuring and reference wavelengths are used for normalizing which is used to remove some effects of noise. Anderson further teaches that an alternative mathematical model involves determining an analyte concentration by taking the logarithmic value of the measured spectral values. (column 20, line 46 to column 21, line 8 of Anderson). These analyzing techniques as disclosed by Anderson are well known in the art and serve the function to analyze spectra data that is required in the multivariate analysis in the combination. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include the analyzing techniques of Anderson since the combination requires spectral analysis to be performed and Anderson teaches well-known techniques for implementing the analysis. The combination of these techniques in which the most appropriate order of analysis can be determined by

routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art.

Response to Arguments

10. Applicant's arguments filed 8/12/2003 have been fully considered but they are not persuasive. Applicant contends that "Essenpreis does not recite as to whether influence of skin (such as difference in the content of melanin in the skin and difference n growth of sin) is eliminated by using the luminous fluxes of the different optical path lengths." The Examiner respectfully disagrees. Essenpreis discloses a calculator for calculating a bilirubin concentration from the signals received. (column 10, lines 2-8 and column 7, line 65 to column 8, line 29 of Essenpries et al.). The calculation concentrates on determining bilirubin but also eliminating other influencing factors, such as temperature. (column 4, lines 30-60 of Essenpries et al.). The elimination of other influencing factors in the final concentration value is considered to be calculating bilirubin so that influence of skin is cancelled by the luminous fluxes..

Allowable Subject Matter

11. Claim 3 and 21-26 are allowed.

12. Claims 2 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Interview

13. The Examiner required some clarification about the new limitation "a calculator for calculating a bilirubin concentration based on the first to fourth electric signals so that influence of skin is cancelled by using the luminous fluxes of the different optical path length" in claim 20. Most spectroscopic devices that analyze analyte concentrations perform measurements that try to cancel external influences and background noises, including skin parameters. As per Applicant's request in Amendment filed on 8/12/2003, the Examiner contacted the Applicant in an attempt to better understand what the limitation was suppose to mean in relation to their invention and possibly amend the claim to clarify the Applicant's position. The Applicant stated that such a discussion was not possible. The Examiner, therefore, has read the claim language in the broadest possible interpretation, which has resulted in the above rejections in this Office Action.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Matthew Kremer
Assistant Examiner
Art Unit 3736

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700